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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,551	04/12/2007	Atsushi Miyawaki	P30056	5047

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EXAMINER	
KIM, ALEXANDER D	
ART UNIT	PAPER NUMBER
1656	

NOTIFICATION DATE	DELIVERY MODE
11/27/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/581,551	MIYAWAKI ET AL.	
	Examiner	Art Unit	
	ALEXANDER D. KIM	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) *1-3,5,6,8,9,12-17 and 19-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4,7,10,11 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/21/2007,4/12/2007,10/24/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Application Status

1. By virtue of a preliminary amendment filed on 6/2/2006, claims 10-12, 17-18, 28-30 and 35-36 have been amended. Claims 1-36 are pending in this instant case.

Election

2. Applicant's election with traverse of Group XVI, (Claims 4, 7, 10, 11 and 18 (in part)) in the reply filed on 7/16/2009 is acknowledged. The traversal is on the ground(s) that all the claims share a unity of invention because of DNA encoding a Kusabira-Orange fluorescent proteins have high degree of homology to each other (% homology is provided in the table, see Remarks filed on 7/16/2009, the last page); thus, special technical feature of DNA encoding said protein are shared among groups of XVI-XXX. This is not found persuasive because, as noted in the previous office action, the special technical feature is the protein having the amino acid sequence of SEQ ID NO: 1 (see page 7, non-final office action mailed on 6/16/2009. Although, nucleic acids of Groups XVI-XXX are similar to each other, each DNA in a group has distinct structure from the special technical feature of nucleic acid encoding the polypeptide of SEQ ID NO: 1. To share unity of invention, the Groups must share the structure of the nucleic acid encoding the polypeptide of SEQ ID NO: 1, which is not the case (e.g., the SEQ ID NO: 1 is not a fragment of any other SEQ ID NOs) and each nucleic acid as set forth in a SEQ ID NO requires different search against database. The requirement is still deemed proper and is therefore made FINAL.

Claims 1-3, 5-6, 8-9, 12-17 and 19-34 are withdrawn from further consideration as non-elected inventions. The claims will be examined only to the extent they read on the elected subject matter. Claims 4, 7, 10, 11 and 18 (in part) will be examined herein.

Priority

3. The instant application is a 371 filing of the International Application No. PCT/JP04/18437 filed on 12/03/2004. The Examiner notes that the requirements of national stage entry of the instant application had been completed (note assigned U.S. filing date) within 30 months of the earliest claimed priority date; the related international application includes both a search report and a preliminary examination report.

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d) to a foreign patent application Japan 2003-404472 (filed on 12/03/2003) and Japan 2004-018344 (filed on 1/27/2004). Said foreign priorities are filed without English translation on 6/2/2006.

Information Disclosure Statement

4. The information disclosure statements (IDSs) filed on 10/24/2006, 04/12/2007 and 06/21/2007 have been reviewed, and its references have been considered except for those which have been lined through. A copy of Form PTO/SB/08 is attached to the instant Office action.

Claim Objections

5. Claims 4, 7, 10, 11 and 18 are objected to because of the following informalities:

Claims 4, 7 and 18 (Claims 10 and 11 dependent therefrom) recite "to those of the protein having the amino acid sequence shown in SEQ ID NO: 1" in (b). There is only one protein having the amino acid sequence shown in SEQ ID NO: 1. Thus, it should recite ---"to the protein having the amino acid sequence shown in SEQ ID NO: 1" to improve the format of the claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 4, 7, 10, 11 and 18 are rejected under 35 U.S.C. § 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 4, 7, 10, 11 and 18 are drawn to a DNA (a vector or a transformant thereof) encoding a protein having an amino acid sequence comprising a deletion, substitution, and/or addition of one or several amino acids with respect to the amino acid sequence shown in SEQ ID NO: 1, which has fluorescence properties equivalent to the polypeptide of SEQ ID NO: 1, and which exists in the form of a monomer.

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as be structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 1997 U.S. App. LEXIS 18221, at *23, quoting Fiers v. Revel, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these (paraphrased from *Enzo Biochemical Inc. v. Gen-Probe Inc.* (CAFC (2002) 63 USPQ2d 1609).

Claims 4, 7, 10, 11 and 18 are drawn to a very widely varying genus of DNA encoding any variants of SEQ ID NO: 1 by deletion, substitution and /or addition of any number amino acid(s) while maintaining the function of fluorescence properties equivalent to the polypeptide of SEQ ID NO: 1 (i.e., a mutant of native fluorescent protein from a coral Fungia sp.), and which exists in the form of a monomer. For claims drawn to a genus, MPEP § 2163 states the written description requirement for a claimed genus may be satisfied through sufficient description of a *representative number of species* by actual reduction to practice, reduction to drawings, or by disclosure of

relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406. MPEP § 2163 states that a representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. In this case, the specification discloses a species (i.e., SEQ ID NO: 1 which is prepared by a degenerate PCR random mutagenesis from the native fluorescent protein from a coral Fungia sp.) encompassed by the very broad genus (i.e., several amino acid deletion, substitution, and /or addition from SEQ ID NO: 1; thus, encompassing any nucleic acid having the function of fluorescence properties equivalent to the polypeptide of SEQ ID NO: 1, which exists in the form of a monomer). However, the specification fails to describe any additional representative species of the claimed genus. While MPEP § 2163 acknowledges that in certain situations "one species adequately supports a genus", it is also acknowledges that "for inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus". In the instant case, the claimed genus DNA encoding any variant of SEQ ID NO: 1 as described above with said function are overly broad variant of nucleic acid. As such, the disclosure of one representative species of mutant DNA is insufficient to be representative of the

attributes and features of all species encompassed by the claimed genus of a DNA. Given the lack of description of a representative number of species, the specification fails to sufficiently describe species to represent the correlation between the structure (e.g., any variant) and function of claimed genus (e.g., fluorescence properties equivalent to the polypeptide of SEQ ID NO: 1, which exists in the form of a monomer), claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicant was in possession of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 4, 7, 10, 11 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Timms-Wilson et al. (Journal of Microbiological Methods, 2001, Vol. 46, pages 77-80).

Claims 4, 7, 10, 11 and 18 are drawn to a DNA (a vector, a transformant and kit thereof) encoding a polypeptide having any variation from SEQ ID NO: 1 having deletion, substitution, and/or addition by any number(s) of amino acids, fluorescence properties equivalent to the polypeptide of SEQ ID NO: 1, which exists in the form of a monomer.

Timms-Wilson et al. et al. teach plasmid pUTgfp/lux which were transformed in to E. coli (see description of Figure 1 on page 78). The plasmid pUTgfp/lux by Timms-Wilson et al. meets the limitation of claimed DNA and vector having appropriate number of deletion, substitution, and/or addition from the nucleotide of SEQ ID NO: 2. The green fluorescent protein (GFP) encoded by the DNA or vector carrying gfp gene also meets the limitation of having fluorescence properties equivalent to the polypeptide of SEQ ID NO: 1 in view of broad definition of "equivalent fluorescence properties" which means that a fluorescent protein has equivalent fluorescence intensity, equivalent excitation wavelength, equivalent fluorescence wavelength, equivalent pH sensitivity, and the like (emphasis added, see page 16, lines 5-9) and in view of broad and reasonable interpretation of the term "equivalent" which includes but not limited as being identical to each other. Timms-Wilson et al. also teach the GFP protein is 30 kDa monomer (see left column, lines 26-27, page 80); thus, meeting the limitation of Claims 4, 7, 10 and 18. Also, the transformed E. coli with vector pUTgfp/lux meets the limitation of Claims 11 and 18.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEXANDER D. KIM whose telephone number is (571)272-5266. The examiner can normally be reached on 10AM-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alexander D Kim/
Examiner, Art Unit 1656